# OUTCOME MEASURES IMPROVE FOLLOWING HOME USE WITH PATTERN RECOGNITION CONTROL

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## ABSTRACT

Nine people with transhumeral amputations and targeted muscle reinnervation participated in a study to determine how outcome measures change pre and post a minimum 6 week home trial. Each subject controlled a prosthetic arm system comprised of commercially available components controlled using a pattern recognition control system. Subjects showed statistically significant improvements ($p<0.05$) in offline classification error, Target Achievement Control test results, the Southampton Hand Assessment Procedure (SHAP) and the Box and Blocks Test. Their performance also showed a trend toward improvement in the Clothespin relocation task and the Jebson-Taylor test; however these changes were not statistically significant.

## INTRODUCTION

Pattern recognition control has been investigated for decades as an alternative to conventional amplitude control for upper-limb multifunction prostheses [1-4]. In pattern recognition control, machine learning techniques are used to decode information from residual limb muscles of the forearm[5, 6], natively innervated biceps and triceps muscles[2], or reinnervated muscle using targeted muscle reinnervation [3]. Several pattern recognition algorithms have been evaluated and many have been shown to accurately classify several movements with greater than 90% classification accuracy [7].

Most pattern recognition studies have been performed over short durations in controlled laboratory settings, often using intact limb control subjects or within virtual environments. Studies completed over multiple days show that subjects form more consistent and accurate patterns with [8, 9] or without [10] real-time control feedback. This would presumably lead to improvements controlling a physical prosthesis. We recently showed that outcome measures taken with a physical prosthesis tended to improve after using a pattern recognition control system during a 6 week home trial for transradial amputees [11].

The objective of this study was to compare a suite of outcome measures pre and post a minimum 6 week home trial. Based on the previously cited studies, we hypothesized that there would be an improvement in outcome measures as patients learned to form more consistent contractions and learned to use their physical prosthesis within their home environment.

## METHODS

Nine individuals with transhumeral level amputations who had previously undergone TMR and provided informed consent were recruited for the study which approved by Northwestern University's Institutional Review Board. Seven different surgeons performed the surgeries. All subjects were previous myoelectric prosthesis users prior to enrolling into the study, but at the time of enrollment, not all subjects were routinely using their prostheses.

The surgical method has previously been described in detail[12]. Briefly, the patients had general anesthesia with no paralytic agents so that nerves could be identified easily with stimulation. An incision was made between the two heads of the biceps. The plane between the long and short head of the biceps was identified, widened and explored to find the musculocutaneous and median nerves. The musculocutaneous nerve to the short head of the biceps was cut as it entered the muscle and the distal segment was buried in the long head so that it did not reinnervate the short head. Next the median nerve was identified and freed distally. It was then cut so that the proximal segment could be transferred to the short head motor point and the median nerve was simply sewn over the small motor point on to the muscle. For some surgeries, the subcutaneous fat was dissected free from distal to proximal and saved as a fat flap. The fat flap was then laid between the short and long heads of the biceps as a physical spacer that help to separate the EMG signals once the recovery was complete and the patient was refit with a prosthesis using TMR. Essentially this same procedure was next done to the triceps so that the distal radial nerve innervating extensor muscles below the elbow was transferred to the lateral triceps and a fat flap separated the lateral triceps from the long head and medial heads of the triceps.

A custom fabricated prosthesis was created for each patient using a Boston Digital Elbow (Liberating Technologies Inc.), a Motion Control Wrist Rotator (Motion Control Inc.), and a single degree-of-freedom terminal

Table I: Patient Demographics

| Patient | Age (years) | Time since amputation (years) | Time since TMR (years) | Side | Gender | Etiology | Terminal Device used |
|---|---|---|---|---|---|---|---|
| P1 | 35 | 4 | 3 | R | M | Trauma (military) | Hook-ETD |
| P2 | 45 | 2 | 1 | R | M | Trauma (train) | Hand |
| P3 | 54 | 6 | <1 | L | M | Trauma (military) | Hook-ETD |
| P4 | 58 | 5 | 1 | L | M | Sarcoma | Hook-ETD |
| P5 | 25 | 6 | 6 | L | M | Trauma | Hook-ETD |
| P6 | 31 | 8 | 7 | L | M | Trauma (military) | Hook-Greifer |
| P7 | 27 | 2 | 1 | R | M | Trauma (crushing) | Hook-Greifer |
| P8 | 31 | 1 | 1 | R | M | Trauma (MVA) | Hook-ETD |
| P9 | 44 | 1 | <1 | R | F | Trauma (infection) | Hand |

device of their choice (Table 1). Consequently the prosthesis is capable of performing the following powered movements: elbow flexion (EF), elbow extension (EE), wrist pronation (WP), wrist supination (WS), terminal device open (TDO), terminal device close (TDC), and no movement (NM). Many of the terminal devices also incorporated passive wrist flexion and extension. All subjects, except P9, were fit with two custom fabricated thermoplastic elastomer gel liners (Alps Inc.). Stainless steel electrodes were embedded into the wall of the liner and stretchable conductive fabric transmitted the EMG signals to the distal end of the liner. P9 was fit with a custom rolled silicone liner to minimize length. Electrode locations were not targeted over specific muscles, rather a grid of electrodes were used as described in previous work[13]. At the distal end of the liners, the signals were amplified and digitized using a Texas Instruments ADS1299 chip sampled at 1000 Hz and transmitted to an embedded controller. The decoded commands were then sent to the prosthesis to control movement and were also logged by the embedded system so that the amount of time the prosthesis was used could be measured. This pattern recognition system was developed internally at the Center for Bionic Medicine and was subsequently released commercially as the Coapt Complete Control System (Coapt, LLC). The amplifier gains were set on a subject specific basis with a typical value of 2000, and data were digitally filtered between 70-450 Hz. A recalibration switch was laminated into the outer wall of each socket so that the users could initiate a pattern recognition calibration routine whenever they desired.

Seven of the nine subjects were naïve to pattern recognition. While the prosthesis was being constructed, these subjects were taught the concept of pattern recognition and instructed to make repeatable and distinct muscle contractions by an occupational therapist [14]. During this prehome phase of training they were given visualization exercises but received no real-time control feedback. After subjects felt that could form consistent contractions, data were collected to train and test a pattern recognition system, and 3 trials of the virtual environment based Target Achievement Control (TAC) Test were completed [15]. The pattern recognition system was identical to the system previously reported [11]. Four repetitions of 3 seconds duration for each movement were used as training data. An additional 4 repetitions of 3 seconds duration for each movement were collected following the final TAC test and were used as the testing data from which the classification error metric was computed.

After being fit with the prosthesis, subjects received intensive occupational therapy and functional use training. These sessions were spread over three or four consecutive days that lasted approximately six hours per day. Individuals took the device home for a minimum of 42 days (6 weeks) of home-use. If the prosthesis needed to be returned for repair or if the user had a valid and documented reason for not wearing a myoelectric prosthesis then additional time was added to the home-trial to ensure that they had 6 weeks of usage. Examples of valid reasons to not wear the prosthesis included extreme sports competitions, taking a beach vacation, being sunburned, etc. Outcomes were measured prior to and after each home-trial. The outcome measures included: the Southampton Hand Assessment Protocol (SHAP), the Jebsen-Taylor Test of Hand Function, three repetitions of the Box and Blocks test, and three repetitions of the Clothespin Relocation task. These measures were selected, in part, based on the recommendations of the American Academy of Orthotists and Prosthetists State of the Science meeting on Upper Limb Prosthetic Outcome Measures (25). These measures were also chosen to evaluate hand, wrist, and elbow function and were activities that could be reasonably completed with a physical prosthesis.

For outcome measures where only a single pre and post test was administered a one-tailed paired-T test was used to check differences. For outcome measures where multiple

trials were recorded, a repeated measures ANOVA was performed to check for significant differences.

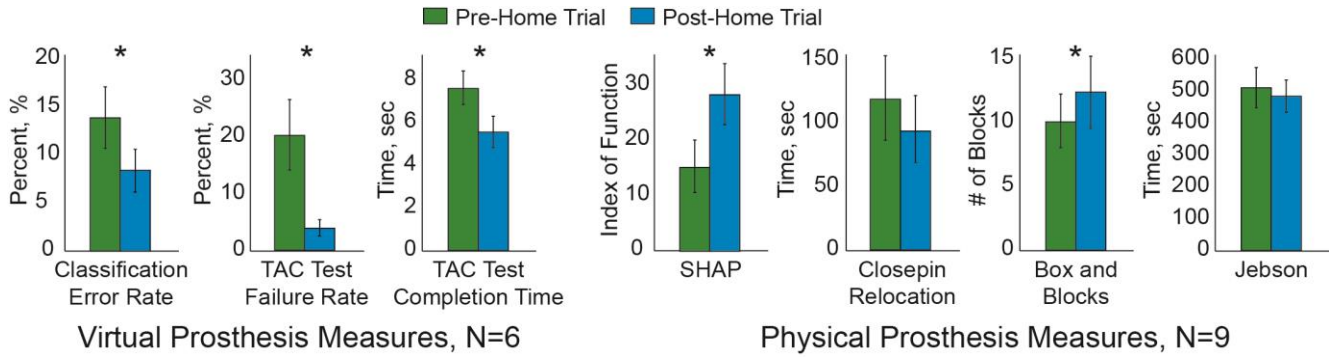


Figure 1: Outcome measures when using a virtual and physical prosthesis. The measures were taken pre and post a minimum 6 week home trial. * Denotes statistical significance between at the p = 0.05 level.

## RESULTS

Classification error rate is the most frequently reported outcome measure to characterize the performance of upper-limb pattern recognition control systems. The classification error metric and TAC test outcome metric were only available from 6 of the 9 subjects. Two subjects had prior experience controlling the virtual prosthesis and data from one subject was lost due to a computer malfunction. From the remaining subjects, we found that the classification error was significantly lower (p=0.03) after the home trial. The Target Achievement Control test was completed in the virtual environment. We found that the failure rate (0<0.001), and completion times (p=0.007) were also significantly lower after the home-trial.

All subjects wore the device at home, and could successfully recalibrate the device (Table 2). Subject 2 typically removed the prosthesis while it was still powered on and it was not possible to accurately determine wear-time for this patient. Occasionally, the recalibration failed. Upon further investigation of the primary cause of these failures was a broken electrode wire.

Table II: Usage Statistics

| Patient | Number of Successful/Attempted PGTs Sessions | Total Number of Days Worn | Total Wear Time in Study (hrs) |
|---|---|---|---|
| P1 | 7/7 | 9 | 45 |
| P2 | 39/39 | 18 | - |
| P3 | 73/77 | 41 | 181 |
| P4 | 56/57 | 58 | 365 |
| P5 | 10/10 | 36 | 88 |
| P6 | 20/20 | 14 | 28 |
| P7 | 18/18 | 20 | 127 |
| P8 | 38/38 | 28 | 69 |
| P9 | 60/60 | 32 | 88 |

All nine subjects completed the outcome measures using the physical prosthesis. All outcome measures associated with using the physical prosthesis tended to improve compared to the pre-home trial testing condition; however there were only statistically significant improvements in the SHAP (p = 0.001) and the Blocks and Box (p =0.03).

## DISCUSSION

Limited previously published data has suggested that patients learn to form more consistent and distinct contractions over time, and have speculated that these would lead to improved control with a pattern recognition controlled physical prostheses. In this contribution, we have shown statistically significant improvements in the SHAP and Blocks and Box test after a minimum 6 week home trial. The results of the clothespin relocation task and the Jebson-Taylor test also showed a trend toward improvement but were not statistically significant.

Virtual environment tests are inexpensive and convenient to use. The performance metrics associated with the TAC Test showed statistically significant improvements after the home-trial. The classification error-rates achieved by the 6 subjects who completed this portion of the study were consistent classification error rates that are typically reported in the literature [3, 7, 10]. The dramatic improvement in failure rate scores and the improvement in completion time score is likely attributed to 2 factors: 1) subject had a more accurate control system that responded better to their intention, and 2) the subjects were more familiar with the TAC test itself as they had already completed the test previously. Given that the tests were spaced by at least 6 weeks, we suspect that the improvements were primarily driven by more accurate control.

The relationship between offline measures of control, such as classification error rate and real-time control performance such as those derived from outcome measures

made when controlling a physical or virtual prosthesis is nebulous. Some studies report correlation [16, 17] whereas other report only a weak or no relationship [18]. Our data suggests that there is a relationship but further works need to be completed to better characterize it.

## CONCLUSION

We have found that providing users with an opportunity to use a pattern recognition controller prostheses in their home-environment can result in improved outcomes. These improvements were seen in offline performance metrics, such as the classification error-rate, and real-time control outcome measures recorded when controlling a virtual or physical prosthesis. When considered with our previous work that also show improvement in outcome measures taken pre and post home trial [11], it is important to allow for adequate practice using a prosthesis prior to recommending the final control strategy.

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